

IN THE UNITED STATES DISTRICT COURT FOR  
THE MIDDLE DISTRICT OF TENNESSEE AT NASHVILLE

IN RE:

AREDIA AND ZOMETA PRODUCTS  
LIABILITY LITIGATION

(MDL No. 1760)

This Document Relates To Case No.:  
Case No.: 3:06-cv-00369 (Parmentier/Johnson)

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) No. 3:06-MD-1760  
)  
) JUDGE CAMPBELL  
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) MAGISTRATE JUDGE BROWN  
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**PLAINTIFF'S OPPOSITION TO DEFENDANT'S  
DAUBERT MOTION TO EXCLUDE THE  
TESTIMONY OF PLAINTIFF'S EXPERT WITNESSES**

Daniel A. Osborn, Esq.  
OSBORN LAW, P.C.  
295 Madison Avenue, 39th Floor  
New York, New York 10017  
Telephone: (212) 725-9800  
Facsimile: (212) 725-9808

LAW OFFICES OF JEFFREY C. BOGERT  
501 Colorado Boulevard, Suite 208  
Santa Monica, California 90401  
Telephone: (310) 395-5025  
Facsimile: (310) 395-5071

THE POWELL LAW FIRM, L.C.  
269 South Beverly Drive, Suite 1156  
Beverly Hills, California 90212  
Telephone: (888) 238-1998  
Facsimile: (310) 388-1570

*Attorneys for Plaintiff Judith Parmentier*

Plaintiff Judith Parmentier (“Plaintiff”)<sup>1</sup> respectfully submits this memorandum in opposition to defendant Novartis Pharmaceuticals Corporation’s (“Defendant” or “Novartis”) *Daubert* motion to exclude case-specific causation testimony by Plaintiff’s retained and non-retained experts. More specifically, Plaintiff opposes Defendant’s motion to exclude the testimony of Dr. Shabtaie, Plaintiff’s retained expert, and Drs. Begley and Peters, two of Ms. Johnson’s treating doctors.<sup>2</sup>

### **PRELIMINARY STATEMENT**<sup>3</sup>

In this product liability action, Plaintiff alleges, and the evidence will show, that Linda Johnson developed osteonecrosis of the jaw (“ONJ”) as a result of being prescribed and treated with Defendant’s drugs Aredia and Zometa. Aredia and Zometa are in a class of drugs called bisphosphonates. ONJ is a serious, painful and debilitating medical condition in which part of the individual’s jaw bone has died. In this case, Linda Johnson’s ONJ appeared on both sides of her lower jaw and ultimately necessitated a debridement. As Linda Johnson’s treating oral and maxillofacial surgeon, Dr. Begley, explained that during the debridement he used cutting tools to

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<sup>1</sup> Judith Parmentier, Linda Johnson’s sister, was substituted as the personal representative of the estate of Linda Johnson after she died.

<sup>2</sup> Plaintiff does not intend to seek case-specific causation testimony from, and therefore withdraws the designations of, Drs. Bell, Holmes and Wick. Plaintiff reserves the right, however, to call any or all of these doctors as a witness at trial to testify about his or her care and treatment of Linda Johnson and their respective diagnoses.

<sup>3</sup> The following documents are attached hereto: (Exhibit 1) Affidavit of Ramin Shabtaie, D.D.S. (“Shabtaie Aff.”), (Exhibit 2) Dr. Shabtaie’s *Curriculum Vitae* (“Shabtaie CV”), (Exhibit 3) Excerpts from the Transcript of the Deposition of Dr. Shabtaie, dated April 18, 2011 in Hendrix, et al. (“Shabtaie Dep.”), (Exhibit 4) Excerpts from the Transcript of the Deposition of Dr. Begley (“Begley Dep.”), (Exhibit 5) Excerpts from the Transcript of the Deposition of Dr. Peters (“Peters Dep.”), (Exhibit 6) Defendant’s Designation of Non-Retained Experts in the *Johnson* matter (“NPC Des.”).

remove dead jaw bone from both sides of Linda Johnson's lower jaw until he reached bleeding bone. Begley Dep. at 25-26.

Plaintiff filed suit against Defendant in federal court, challenging Defendant's development, testing, manufacturing, labeling and marketing of Aredia and Zometa. Specifically, Plaintiff's common law claims include claims for strict product liability (design defect), strict product liability (failure to warn), negligence, breach of express warranty and breach of implied warranty. This case was subsequently transferred into this multi-district product liability litigation.

Plaintiff intends to rely, in part, on the expert testimony of Dr. Shabtaie to prove case-specific causation, i.e., that Zometa caused Linda Johnson's ONJ. Dr. Shabtaie was retained and designated as an expert in this case; he provided an expert affidavit; and was deposed by Novartis. Plaintiff also intends to rely, in part, on the testimony of Dr. Begley and Dr. Peters to prove case-specific causation. Dr. Begley treated Ms. Johnson's ONJ and Dr. Peters was Ms. Johnson's oncologist; he prescribed, altered and ultimately stopped the Aredia and Zometa treatments. Neither doctor has been retained as an expert in this case; however, both were designated as non-retained experts by Plaintiff (as well as by Defendant). In addition, Dr. Begley and Dr. Peters have been deposed in this case and have produced a copy of their medical records.

Dr. Shabtaie, Dr. Begley and Dr. Peters are qualified to give case-specific causation opinion testimony in this case and their testimony, i.e., that Linda Johnson suffered from bisphosphonate induced ONJ, meets the requirements under Rule 702 of the Federal Rules of Evidence and *Daubert*. Therefore, Defendant's motion should be denied.

## **WITNESSES**

### **I. Dr. Shabtaie.**

**Dr. Shabtaie's Qualifications.** Dr. Shabtaie is an oral and maxillofacial surgeon licensed to practice in the State of California. Shabtaie CV. He has been practicing oral and maxillofacial surgery for at least eleven years. *Id.* In addition to his private practice, Dr. Shabtaie is on the staff of the UCLA Medical Center as a part-time attending physician and is a Clinical Instructor with the UCLA Oral and Maxillofacial Surgery Department. *Id.* Dr. Shabtaie is a member of several medical and dental professional organizations, including, among others, the California Association of Oral and Maxillofacial Surgeons, the California Dental Association and the West Los Angeles Dental Society. *Id.*

Dr. Shabtaie graduated from the California State University, Northridge in 1992 with a Bachelor of Science degree in Cellular and Molecular Biology. *Id.* He attended the UCLA School of Dentistry and received his D.D.S. degree in 1996. *Id.* Dr. Shabtaie completed a four year Residency with the UCLA Oral and Maxillofacial Surgery Department in 2000, serving as the Chief Resident in his final year. *Id.*

Since June 2000, Dr. Shabtaie has been continuously engaged in the practice of oral and maxillofacial surgery and has had his own practice in Los Angeles, California since January, 2001. *Id.* In addition to his own practice, Dr. Shabtaie has also performed oral and maxillofacial surgery for several other dental practices over the last ten years. *Id.* He has also been on the staff at the UCLA Medical Center since approximately 2003. Shabtaie Dep. at 87-88, 91. In his private practice, Dr. Shabtaie sees approximately 50 to 60 new patients per month and 500 to 600 patients a year. Shabtaie Dep. at 64. While the majority of his practice involves performing

extractions and placing implants, Dr. Shabtaie also treats patients who have trauma related problems and various oral pathologies, including oral lesions. *Id.* at 64-66.

Starting in 2002, Dr. Shabtaie started working part-time as a clinical instructor at Cedars-Sinai Medical Center – Department of Oral Surgery/Dentistry and at the UCLA School of Dentistry, Department of Oral and Maxillofacial Surgery. Shabtaie CV. Although Dr. Shabtaie ceased being a clinical instructor at Cedars-Sinai in 2006, he is still a clinical instructor at UCLA. *Id.* As part of his responsibilities as a clinical instructor, Dr. Shabtaie presents a lecture, each quarter, to the third-year students at the UCLA School of Dentistry. Shabtaie Dep. at 43-47. Since 2004, Dr. Shabtaie's lecture has included a discussion about ONJ and, more specifically, bisphosphonate induced ONJ. *Id.* Dr. Shabtaie's lectures discusses how to evaluate patients for ONJ, how to assess who may be at risk for ONJ, and potential ways to treat the condition once it is diagnosed. *Id.*

While Dr. Shabtaie learned about ONJ in dental school, he first became aware of bisphosphonate induced ONJ ("BIONJ"), also known as bisphosphonate related ONJ ("BRONJ"), in early 2004. Shabtaie Aff. at ¶ 5. Dr. Shabtaie subscribes to numerous dental journals that report the latest findings on bisphosphonates and ONJ. Over the years, Dr. Shabtaie has kept abreast of the medical literature relating to bisphosphonate induced ONJ and, in fact, has kept a file with some of that literature. Shabtaie Dep. at 19-31. Among the materials Dr. Shabtaie has kept are articles from 2003 to 2011. *Id.* Dr. Shabtaie has also written an article about the relationship between bisphosphonates and osteonecrosis of the jaw, titled *Osteonecrosis – A Complication of Bisphosphonate Therapy*. Shabtaie Dep. at 38-40. His article was published in *West Views*, a publication by the Western Los Angeles Dental Society.

*Id.* Dr. Shabtaie acted as the editor of West Views in 2006 and 2007. Shabtaie CV and Shabtaie Dep. at 136.

Over the last six years, Dr. Shabtaie has been involved in the treatment of six patients who had ONJ. Shabtaie Dep. at 72. Of those six patients, three were Dr. Shabtaie's patients in his private practice and he saw three of those patients as an Attending Physician at the UCLA Department of Oral Surgery. Shabtaie Dep. at 72-73, 84-86. In addition, of the six ONJ patients seen by Dr. Shabtaie, five suffered from bisphosphonate related ONJ. Shabtaie Dep. at 72-73, 90.

**Dr. Shabtaie's Opinions in this Case.**

In this case, Dr. Shabtaie concluded, to a reasonable degree of medical certainty, that Linda Johnson developed ONJ as a result of being treated with a bisphosphonate, in this case Zometa (and perhaps Aredia as well). Shabtaie Rpt. at ¶ 10.

In connection with his work in this case, Dr. Shabtaie reviewed Ms. Johnson's relevant medical records, including the charts and records of Dr. Ray Peters, Dr. Laura Holmes, Dr. Donna Almond, Dr. Dennis Leutkemeyer, Dr. Benny Bell, and Dr. Randall Begley. *Id.* at ¶ 13. Dr. Shabtaie also reviewed the transcripts of the depositions of Dr. Begley and Dr. Bell. *Id.* Dr. Shabtaie relied on his more than ten years of experience as an oral and maxillofacial surgeon (and his training), his experience evaluating and treating patients with bisphosphonate related ONJ (as well as patients with necrotic bone in their jaws for other reasons), the available medical literature on bisphosphonate related ONJ, his knowledge of bone biology, and information he learned through collaborations with his colleagues. Shabtaie Rpt. at ¶¶ 5-9.

In reaching his conclusions about Ms. Johnson, Dr. Shabtaie performed a differential diagnosis. Shabtaie Rpt. ¶ 20. Performing differential diagnoses is something that Dr. Shabtaie does routinely in his practice. Shabtaie Dep. at 75-77. In this case, Dr. Shabtaie considered other possible explanations for Ms. Johnson's ONJ in addition to her treatment with Aredia and Zometa, and ruled them out. Shabtaie Rpt. at ¶ 20. Among the other explanations considered by Dr. Shabtaie was radiation. *Id.* Dr. Shabtaie ruled out radiation because there is no evidence that Ms. Johnson received radiation therapy to her jaw. *Id.* Moreover, there is no evidence that Ms. Johnson suffered from mucositis or xerostomia (signs of excessive exposure to radiation). *Id.*

## **II. Dr. Begley.**

Dr. Begley is a practicing oral and maxillofacial surgeon and has been since 2001. Begley Dep. at 6-7. Dr. Begley graduated from the University of Missouri, Kansas City, dental school in 1991. *Id.* Dr. Begley then served in the United States Navy and practiced dentistry. *Id.* In 1995, Dr. Begley started a dual-degree program, attending medical school and doing his oral maxillofacial surgery residency. *Id.* Dr. Begley obtained his oral maxillofacial surgery certification in 2001 and he is now board certified. *Id.* Since he began practicing, Dr. Begley has treated five or six patients with BRONJ, including Ms. Johnson. Begley Dep. at 27.

Dr. Begley treated Ms. Johnson beginning in January, 2004. Begley Dep. at 9, 14. She was referred by her oncologist because of exposed bone in her lower jaw. Begley Dep. at 10. Dr. Begley ultimately saw Ms. Johnson seven times and performed a debridement on both sides of her lower jaw. Begley Dep. 22, 25-26. Because Ms. Johnson was Dr. Begley's first patient with BRONJ, he did not recognize it at that time. Begley Dep. at 27. Subsequently, however,

based on what he has learned (both from treating other patients and continuing education), Dr. Begley does believe that Zometa was a cause of Ms. Johnson's ONJ. Begley Dep. at 29-30.

As noted above, while Novartis challenges Plaintiff's designation of Dr. Begley as a non-retained expert, Novartis itself designated Dr. Begley as a non-retained expert. NPC Des. at 2. According to its designation, Defendant:

may elicit expert testimony from Dr. Begley regarding: (i) whether Ms. Johnson suffered from periodontal disease and other dental conditions; (ii) his experience as an oral surgeon who has commonly seen jaw osteonecrosis in patients who have never taken bisphosphonates; (iii) his experience as an oral surgeon who has commonly seen osteoradionecrosis in patients; (iv) the adverse effects of chemotherapy and anti-cancer therapy on a patient's oral health; (v) whether there is any non-speculative basis for determining the condition of Ms. Johnson's teeth and oral cavity in the period preceding Ms. Johnson's Aredia and Zometa therapy; and (vii) whether there is any non-speculative basis for concluding that Ms. Johnson's jaw problems would have persisted without healing had she not died from breast cancer..

*Id.*

### **III. Dr. Peters.**

Dr. Peters is a practicing medical oncologist and has been for more than 20 years. Peters Dep. at 5-10. He is Board certified in internal medicine and medical oncology. *Id.* at 6. Dr. Peters began treating Linda Johnson in November, 2001 (*Id.* at 16) and continued to provide care to her until she passed away in 2007.

Dr. Peters graduated from the University of Illinois in Champagne-Urbana in 1967. *Id.* at 5. He then served in the United States Navy. *Id.* Dr. Peters graduated from the Chicago College of Osteopathic Medicine in 1977. *Id.* at 5. After getting his DO degree, Dr. Peters did a rotating internship at the Oklahoma Osteopathic Hospital in Tulsa. *Id.* at 6. Dr. Peters also did a two



year post-graduate fellowship in oncology at MD Anderson Hospital and Tumor Institute in Houston, Texas. *Id.*

While treating Linda Johnson, Dr. Peters concluded that she had ONJ and that it was caused by her treatment with bisphosphonates, i.e., Aredia and Zometa. *Id.* at 67-69. Dr. Peters ruled out metastases to Ms. Johnson's jaw. *Id.* at 50, 52, 69.

As with Dr. Begley, Novartis challenges Plaintiff's designation of Dr. Peters after itself having designated Dr. Peters as a non-retained expert. NPC Des. at 1-2. According to its designation, Defendant:

may elicit expert testimony from Dr. Peters regarding: (i) the benefits of Aredia and Zometa generally and with respect to Ms. Johnson; (ii) the risks and benefits of other medications and treatments received by Ms. Johnson; (iii) the diagnosis, treatment and complications of metastatic breast cancer; (iv) Dr. Peters' decision to continue prescribing Aredia and Zometa to patients even after he learned about osteonecrosis of the jaw ("ONJ") as a possible side effect of Aredia and Zometa; (v) whether he would have prescribed Aredia and Zometa to Ms. Johnson even if he had known about ONJ as a possible side effect; (vi) the potential impact of pathologic fracture, spinal cord compression, and other skeletal-related events on Ms. Johnson's life; (vii) the progression of Ms. Johnson's bone metastases; and (viii) the cause(s) of Ms. Johnson's death..

*Id.*

## **ARGUMENT**

### **I. EXPERT TESTIMONY**

#### **Expert Testimony Generally Under Rule 702 and *Daubert*.**

Expert testimony is governed, primarily, by Rule 702 of the Federal Rules of Evidence. Rule 702 states:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form

of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. Rule 702 changed the ground rules for the admissibility of expert testimony, easing the prior restrictions. Rule 702 “was intended to liberalize the introduction of relevant expert evidence,” not create new barriers. *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4<sup>th</sup> Cir. 1999). Moreover:

Daubert was designed to exclude ‘junk science.’ It was never intended to keep from the jury the kind of evidence scientists regularly rely on in forming opinions of causality . . . .

\* \* \*

Rule 702, a rule of threshold admissibility, should not be transformed into a rule for imposing a more *exacting standard* of causality . . . .

*In re Ephedra Prods. Liab. Litig.*, 393 F. Supp. 2d 181, 190 (S.D.N.Y. 2005) (emphasis added).

Before Rule 702, “the dominant standard for determining the admissibility of novel scientific evidence at trial” was the so-called *Frye*<sup>4</sup> test. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 585 (1993). Pursuant to the *Frye* test, expert testimony was admissible only if it was based on scientific principles and methods that had gained general acceptance in the relevant scientific field. *See Daubert*, 509 U.S. at 585-86.

In *Daubert*, the Supreme Court held that the *Frye* test was superseded by the adoption of the Federal Rules of Evidence, calling the *Frye* test an “austere standard . . . incompatible with[] the Federal Rules of Evidence . . . .” *Daubert*, 509 U.S. at 587, 589. As the Supreme Court

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<sup>4</sup> *See Frye v. United States*, 293 F. 1013 (C.A.D.C. 1923).

explained, the Federal Rules of Evidence, including Rule 702, have a “liberal thrust” and generally relax the traditional barriers to opinion testimony. *Id.* at 588. Furthermore, “it would be unreasonable to conclude that the subject of scientific testimony must be ‘known’ to a certainty; [because] arguably, there are no certainties in science.” *Id.* at 590.

Although the Federal Rules of Evidence greatly eased the restrictions on the admissibility of expert testimony, they did not eliminate all limitations on the introduction of expert testimony, nor did they eliminate the trial judge’s role in screening such evidence. *See id.* at 589. To the contrary, “under the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.” *Id.* In *Daubert*, the Supreme Court articulated a two prong test for the admissibility of expert testimony. Such testimony is admissible under Rule 702 if: (1) the reasoning or methodology underlying the testimony is scientifically valid [the “reliability” prong]; and (2) the reasoning or methodology can properly be applied to the facts in issue [the “relevancy” prong]. *Id.* at 592-93. As the Supreme Court further explained:

The inquiry envisioned by Rule 702 is, we emphasize, a flexible one. Its overarching subject is the scientific validity and thus the evidentiary relevance and reliability of the principles that underlie a proposed submission. The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.

*Id.* at 594-95; *see also In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529-30 (6th Cir. 2008) (“The task for the district court in deciding whether an expert’s opinion is reliable is not to determine whether it is correct, but rather to determine whether it rests upon a reliable foundation, as opposed to, say, unsupported speculation.” Moreover, “rejection of expert

testimony is the exception, rather than the rule’, and we will generally permit testimony based on allegedly erroneous facts when there is some support for those facts in the record.” (citation omitted)). Moreover, “[a]dmissibility under Rule 702 does not require perfect methodology. Rather, the expert must ‘employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.’” *Best v. Lowe’s Home Ctrs., Inc.*, 563 F.3d 171, 181 (6th Cir. 2009).

Finally, in response to concerns that abandoning the *Frye* test would lead to a “free-for-all” in which juries would be confused by so-called junk science, the Supreme Court reminded us that “[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Daubert*, 509 U.S. at 596. In addition, district courts remain free, under appropriate circumstances, to grant motions for summary judgment or directed verdict if the evidence presented is insufficient to support a party’s position. *Id.* As the Supreme Court stated, “[t]hese conventional devices, rather than wholesale exclusion under an uncompromising ‘general acceptance’ test, are the appropriate safeguards where the basis of scientific testimony meets the standards of Rule 702.” *Id.*

#### **Medical Expert Testimony Under Rule 702 and *Daubert*.**

“As a general matter, ‘[p]hysicians and other medical professionals routinely testify as experts since their specialized knowledge generally helps the jury resolve medical issues.’” *Jahn v. Equine Servs., PSC*, 233 F.3d 382, 389 (6th Cir. 2000) (citation omitted). Often, medical and dental experts are called on to give opinions relating to causation. See *Gass v. Marriott Hotel Servs., Inc.*, 558 F.3d 419, 426 (6<sup>th</sup> Cir. 2009) (“Generally, a treating physician may provide

expert testimony regarding a patient's illness, the appropriate diagnosis for that illness, and the cause of the illness.”)

One method for determining causation commonly relied on by medical and dental experts is called a “differential diagnosis.” As explained by the Sixth Circuit, a differential diagnosis “is defined as: [t]he method by which a physician determines what disease process caused a patient's symptoms. The physician considers all relevant potential causes of the symptoms and then eliminates alternative causes based on a physical examination, clinical tests, and a thorough case history.” *Hardyman v. Norfolk & W. Ry. Co.*, 243 F.3d 255, 260 (6th Cir. 2001).

The Sixth Circuit “recognizes differential diagnosis as ‘an appropriate method for making a determination of causation for an individual instance of disease.’” June 29, 2009 *Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 178 (6th Cir. 2009) (citing *Hardyman*, 243 F.3d at 260). As the court in *Best* acknowledged, “[d]ifferential diagnosis is considered to be ‘a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated.’” *Id.* Moreover, “[a]n ‘overwhelming majority of the courts of appeals’ agree, and have held ‘that a medical opinion on causation based upon a reliable differential diagnosis is sufficiently valid to satisfy the first prong [reliability] of the Rule 702 inquiry.’” *Id.* (citation omitted).

However, “[n]ot every opinion that is reached via a differential-diagnosis method will meet the standard of reliability required by *Daubert*.” *Id.* at 179. The Sixth Circuit has adopted the following test regarding the reliability of an opinion based upon a differential diagnosis:

A medical-causation opinion in the form of a doctor's differential diagnosis is reliable and admissible where the doctor (1) objectively ascertains, to the extent possible, the nature of the patient's injury . . . (2) “rules in” one or more causes of the injury

using a valid methodology, and (3) engages in “standard diagnostic techniques by which doctors normally rule out alternative causes” to reach a conclusion as to which cause is most likely.

*Id.* Although a proper differential diagnosis requires the medical or dental professional to consider and rule out, to the extent possible, alternative causes, “[i]n order to be admissible on the issue of causation, an expert’s testimony need not eliminate all other possible causes of the injury.” *Jahn*, 233 F.3d at 390 (finding that two doctors should have been allowed to testify to what they believed was the probable cause of death); *see also Best*, 563 F.3d at 181. Even if “several possible causes” are not ruled out by proffered expert testimony, that fact “only goes to the accuracy of the conclusion, not to the soundness of the methodology” and, thus, the testimony’s admissibility. *Jahn*, 233 F.3d at 390 (citation omitted).

Ultimately, “[m]edical opinions need not be unchallengeable in order to be admissible. Medical experts are just witnesses, and they need not be purveyors of ultimate truth in order to be allowed on the stand.” *Id.* at 393.

## **II. DR. SHABTAIE’S EXPERT OPINIONS IN THIS CASE MEET THE REQUIREMENTS OF RULE 702 AND DAUBERT**

Defendant contends that Dr. Shabtaie’s case-specific causation opinion in this case is unreliable because “his differential diagnosis is fraught with critical omissions regarding other risk factors for ONJ.” Defendant’s Memorandum at 2, 7-10. The fact that Defendant is unconvinced by Dr. Shabtaie’s reasons for ruling out other so-called risk factors as the cause of Linda Johnson’s ONJ is not grounds for excluding Dr. Shabtaie’s testimony. At most, these arguments go to the weight of Dr. Shabtaie’s testimony and should be made to a jury.

In reaching his opinions in this case, Dr. Shabtaie reviewed Ms. Johnson's relevant medical records, including the charts and records of Dr. Ray Peters, Dr. Laura Holmes, Dr. Donna Almond, Dr. Dennis Leutkemeyer, Dr. Benny Bell, and Dr. Randall Begley. Shabtaie Rpt. at ¶ 13. As noted above, Dr. Peters was Ms. Johnson's primary oncologist and Dr. Begley treated Ms. Johnson's ONJ. Dr. Shabtaie also reviewed the transcripts of the depositions of Dr. Begley and Dr. Bell, another of Ms. Johnson's treating dentists. *Id.* Dr. Shabtaie also relied on his years of experience as an oral and maxillofacial surgeon, including his experience evaluating and treating patients with bisphosphonate related ONJ, the available medical literature on bisphosphonate related ONJ, and his knowledge of bone biology. Shabtaie Rpt. at ¶¶ 5-9. Defendant's contention that Dr. Shabtaie merely relied on the opinions of Drs. Begley and Peters is baseless. While Dr. Shabtaie certainly considered the opinions of these important treating doctors, there is nothing to support Defendant's contention that Dr. Shabtaie is merely parroting those doctors. See Defendant's Memorandum at 18-19. To the contrary, as noted here, Dr. Shabtaie reviewed the evidence in this case and relied on his own knowledge and experience.

Moreover, as Defendant concedes, Dr. Shabtaie performed a differential diagnosis. Defendant's Memorandum at 2, 7-10. Among the other explanations for Ms. Johnson's ONJ that were considered and ruled out by Dr. Shabtaie are: radiation therapy, corticosteroids, jaw metastases, and osteomyelitis. Defendant's Memorandum at 8-10. While Defendant is unpersuaded by Dr. Shabtaie's reasoning for ruling out these alternative explanations, as noted above that goes to the weight, not the admissibility, of his testimony.

For these reasons, Defendant's motion to exclude the testimony of Dr. Shabtaie should be denied.

**III. DR. BEGLEY AND DR. PETERS ARE QUALIFIED TO OFFER  
CASE-SPECIFIC CAUSATION TESTIMONY IN THIS CASE**

Defendant argues that Dr. Begley and Dr. Peters are not qualified to offer expert case-specific testimony in this case and that Dr. Begley did not reach his causation opinion while treating Linda Johnson. Contrary to Defendant's position, Drs. Begley and Peters are qualified to give case-specific causation opinions in this case. In addition, while Dr. Begley did in fact reach his conclusion as to the cause of Linda Johnson's ONJ after he treated her, he merely relied on his observations of Ms. Johnson's condition from when he treated her.

**Dr. Begley and Dr. Peters are Qualified.**

Defendant's argument that Dr. Begleys and Dr. Peters are not qualified to offer expert case-specific causation testimony is particularly noteworthy because Novartis itself included both doctors in its own Designation of Non-Retained Experts. See NPC Des. With respect to Dr. Begley, Novartis stated that he would testify about, among other things, "whether Ms. Johnson suffered from periodontal disease and other dental conditions," as well as his experience as an oral surgeon who has commonly seen patients with jaw necrosis and osteoradionecrosis. NPC Des. at 2 (emphasis added). As for Dr. Peters, Defendant designated him as a non-retained expert on the topics of "the benefits of Aredia and Zometa" and "the risks and benefits of other medications and treatments received by Ms. Johnson." NPC Des. at 1 (emphasis added). In addition, Defendant expects Dr. Peters to testify about his "decision to continue prescribing Aredia and Zometa to patients even after he learned about osteonecrosis of the jaw (ONJ) as a possible side effect." *Id.* While Novartis will undoubtedly respond by claiming that these physicians are not being retained to testify about causation, there can be little doubt that that will



be the import of their testimony. In short, based on these designations, Defendant has effectively conceded that Dr. Begley and Dr. Peters are qualified to offer opinion testimony on case-specific causation in this case.

Moreover, it was not the intent of Rule 702 or the *Daubert* decision to so limit testimony from treating physicians. As one district court explained:

It is significant in this case that [the doctor] is [plaintiff's] treating physician, not simply an expert who makes a living providing opinion testimony or one retained for purposes of litigation to provide an opinion based on facts presumed to be in evidence. His examination and diagnosis were part of his routine activities as a doctor, which should not be subject to an extensive analysis under *Daubert* and *Kumho Tire*. Though *Daubert* and Rule 702 require district courts to exercise a "gatekeeper" role as to expert testimony, it is generally appropriate "to avoid unnecessary 'reliability' proceedings in ordinary cases where the reliability of an expert's methods is properly taken for granted.

*Flowers v Wal-Mart Stores, Inc.*, 2005 WL 2787101, at \* 7 (M.D. Ga. Oct. 27, 2005) (citations omitted). In this case, Dr. Begley and Dr. Peters were treating physicians, they have not been retained as experts and did not sit down (with a lawyer) to construct their opinions in such a way as to ensure that they met some exacting legal standard. Instead, Dr. Begley and Dr. Peters reached their conclusions in the normal, and expected, course of their care for Linda Johnson. As treating physicians, Dr. Begley and Dr. Peters are entitled to some deference and some leeway in how their opinions are evaluated.

### **CONCLUSION**

Based on the foregoing, this Court should deny Novartis' motion to exclude the causation testimony of Plaintiff's retained expert, Dr. Shabtaie, and his non-retained, treating experts Dr. Begley and Dr. Peters.

Dated: August 1, 2011

Respectfully Submitted,

By: s/ Daniel A. Osborn  
Daniel A. Osborn  
OSBORN LAW, P.C.  
295 Madison Avenue, 39th Floor  
New York, New York 10017  
Telephone: (212) 725-9800  
Facsimile: (212) 725-9808

LAW OFFICES OF JEFFREY C. BOGERT  
501 Colorado Boulevard, Suite 208  
Santa Monica, California 90401  
Telephone: (310) 395-5025  
Facsimile: (310) 395-5071

THE POWELL LAW FIRM, L.C.  
269 South Beverly Drive, Suite 1156  
Beverly Hills, California 90212  
Telephone: (888) 238-1998  
Facsimile: (310) 388-1570

*Counsel for Plaintiff Judith Parmentier*

**CERTIFICATE OF SERVICE**

On this 1<sup>st</sup> day of August, 2011, I certify that I served all counsel of record, including counsel for defendant, by filing the foregoing **PLAINTIFF'S OPPOSITION TO DEFENDANT'S DAUBERT MOTION TO EXCLUDE THE TESTIMONY OF PLAINTIFF'S EXPERT WITNESSES** by using this Court's ECF system.

OSBORN LAW, P.C.

By: s/ Daniel A. Osborn  
Daniel A. Osborn  
295 Madison Avenue, 39th Floor  
New York, New York 10017  
Telephone: (212) 725-9800  
Facsimile: (212) 725-9808